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1 Identification

- Other means of identification
- · Trade name: OpalTM Bond Flow & OpalTM Bond Flow Blue
- · Article number: SDS 75-001.12R01, 71161, 500082-JP, 50211, 500041, 71050, 13859, 500082, 500041-JP
- · Relevant identified uses of the substance or mixture and uses advised against Professional Orthodontic Adhesive
- $\cdot \textit{Application of the substance / the mixture } \textit{Professional Orthodontic Adhesive}$
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ultradent Products, Inc. 505 W. Ultradent Drive (10200 S) South Jordan, UT 84095-3942 USA onlineordersupport@ultradent.com

onlineordersupport@ultradent.co (800) 552-5512

Ultradent Australia Pty Ltd. Level 22/2 Market Street Sydney NSW 2000 Australia

Email: info.anz@ultradent.com Toll Free: 1-800-290929

- · Further information obtainable from: Customer Service
- · Emergency telephone number:

CHEMTREC (NORTH AMERICA): +1 (800) 424-9300 (INTERNATIONAL): +(703) 527-3887

2 Hazard(s) Identification

· Classification of the substance or mixture



Skin corrosion/irritation – Category 2 H315 Causes skin irritation.

Eye damage/irritation - Category 2A H319 Causes serious eye irritation.

Skin sensitisation – Category 1 H317 May cause an allergic skin reaction.

- · Label elements
- · GHS label elements Void
- · Hazard pictograms GHS07
- · Signal word Warning
- · Hazard-determining components of labelling:

Triethylene Glycol Dimethacrylate (>1-<20 %)

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

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· Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves / eye protection / face protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- **Description:** Mixture of substances listed below with nonhazardous additions.

· Dangerous	· Dangerous components:		
109-16-0	Triethylene Glycol Dimethacrylate	>1-<20%	
	♦ Skin sensitisation – Category 1, H317		
	Trade Secret	>0.1-<5%	
	♦ Skin corrosion/irritation – Category 1A, H314; Eye damage/irritation – Category 1, H318		
10287-53-3	Ethyl-4-Dimethylamino Benzoate	≥0.1-<1%	
	♦ Reproductive toxicity – Category 1B, H360		
	Organophosphine Oxide	≥0.1-<1%	
	♦ Skin sensitisation – Category 1, H317		

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- · General information: Immediately remove any clothing soiled by the product.
- · After inhalation:

This product is a thick paste, therefore inhalation is extremely unlikely.

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing: If swallowed in large quantities seek medical attention.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire Fighting Measures

· Suitable extinguishing agents:

Foam, dry chemical, carbon dioxide

Use fire extinguishing methods suitable to surrounding conditions.

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- · Special hazards arising from the substance or mixture No further relevant information available.
- · Protective equipment: Wear fully protective suit.

6 Accidental Release Measures

- · Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and Storage

- · Handling:
- · Precautions for safe handling:

Avoid release to the environment

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- · Information about fire and explosion protection: No special measures required.
- Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions:

See product labelling.

Keep container tightly sealed.

· Specific end use(s) Professional Orthodontic Adhesive

8 Exposure controls and personal protection

- · Appropriate engineering controls No further data; see section 7.
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · Personal protective equipment:
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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Safety Data Sheet according to WHS Regulations

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· Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and Chemical Properties

· General Information

· Appearance:

· Form: Paste

· Colour: According to product specification

· Odour: Acrylic

· *Odour threshold:* Not determined.

· pH-value: Not applicable (non-aqueous)

· Change in condition

Melting point/freezing point:
 Initial boiling point and boiling range:
 Flash point:
 Flammability
 Decomposition temperature:
 Undetermined.
 Not applicable.
 Not determined.

• **Ignition temperature:** Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Laptosion times.

Lower:

Voper:

Not determined.

Vapour pressure:

Not determined.

· Solubility in / Miscibility with

water: Not miscible or difficult to mix.

· Partition coefficient: n-octanol/water: Not determined.

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Viscosity:
Dynamic:
Kinematic:
Not determined.
Not determined.

· Other information

• Particle characteristics Not applicable.

· Physical state Fluid

10 Stability and Reactivity

- · Reactivity Stable
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions: No dangerous reactions known.
- · Conditions to avoid:

Light

Sparks

Ignition sources

Heat

Flames

- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological Information

- · Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC5	· LD/LC50 values relevant for classification:					
109-16-	109-16-0 Triethylene Glycol Dimethacrylate					
Oral	LD50	>5,000 mg/kg (rat)				
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)				
Dermal	LD50	>2,000 mg/kg (mouse)				
Organo	Organophosphine Oxide					
Oral	LD50	>2,000 mg/kg (rat)				
	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)				
Dermal	LD50	>2,000 mg/kg (rat)				

- · Primary irritant effect:
- · Skin corrosion/irritation Causes skin irritation.
- · Serious eye damage/irritation Causes serious eye irritation.
- · Respiratory or skin sensitisation May cause an allergic skin reaction.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

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12 Ecological Information

· Toxicity

· Aquatic toxicity:					
109-16-0 Triethylene Glycol Dimethacrylate					
EC50	>100 mg/kg (Algae)				
Biodegradability	28 days (Aerobic) (Biodegradability testing)				
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)				
Organophosphine Oxide					
EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)				
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)				
Toxicity to Aquatic Plants (sta	tic) >0.26 mg/l (Plant) (Toxicity to algae)				

- · Persistence and degradability No further relevant information available.
- Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Dispose of contents/container in accordance with international, federal, state, and local regulations.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

· UN-Number		
· ADG, ADN, IMDG, IATA	not regulated	
· UN proper shipping name		
· ADG, ÂDN, IMDG, IATA	not regulated	
Transport hazard class(es)		
· ADG, ADN, IMDG, IATA		
Class	not regulated	
Packing group		
· ADG, ĬMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	

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· Special precautions for user Not Applicable

· Transport in bulk according to Annex II of Marpol

and the IBC Code Not applicable.

· UN "Model Regulation": not regulated

15 Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

· NIOSH-Ca (National Institute for Occupational Safety and Health)				
14808-60-7	Silica Glass			
Australian Inventory of Industrial Chemicals				
65997-17-3	Inorganic Glass			
109-16-0	Triethylene Glycol Dimethacrylate			
41637-38-1	EOBPADMA			
	Trade Secret			
	Co-Cr-AL Spinel Blue Green			
13463-67-7	Titanium Dioxide			
10287-53-3	Ethyl-4-Dimethylamino Benzoate			
	Organophosphine Oxide			
10373-78-1	Camphorquinone			
14808-60-7	Silica Glass			
1332-37-2	Red Iron Oxide			
51274-00-1	Yellow Iron Oxide			
	Chromium Iron Oxide			

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Chemical safety assessment:

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases from Section 3

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H360 May damage fertility or the unborn child.

- · Department issuing SDS: Environmental, Health, and Safety
- · Contact: Customer Service

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· Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

Skin corrosion/irritation - Category 1A: Skin corrosion/irritation - Category 1A

Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2

Eye damage/irritation - Category 1: Serious eye damage/eye irritation - Category 1

Eye damage/irritation - Category 2A: Serious eye damage/eye irritation - Category 2A

Skin sensitisation – Category 1: Skin sensitisation – Category 1

Reproductive toxicity - Category 1B: Reproductive toxicity - Category 1B

* Data compared to the previous version altered.

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